

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 19, 2010


SUBJECT: Preliminary Human Health Assessment for the Registration Review of Vegetable and Flower Oils

Registration Review Case #: 8201

PC Codes: 004901, 011332, 021901, 025000, 031602, 031603, 031604, 031605, 031608, 040500, 040502, 040503, 040517, 067200, 072401, 102701, 120011, 128800, 129029, 129030, 597500, 597501, 597800

CAS #: 57-06-7, 120962-03-0, 8000-29-1, 120-72-9, 8001-29-4, 8001-26-1, 8001-78-3, 8001-22-7, 8001-79-4, 8022-15-9, 8007-02-1, 8000-48-4, 8008-57-9, 61789-91-1, 8008-74-0, 97-53-0, 35237-64-0, none, 8007-75-8, 127-41-3, 8000-46-2, 106-24-1, 8007-46-3

Chemical Class: Biochemicals

FROM: Sadaf Shaukat, Biologist   
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

The following is a preliminary human health assessment for vegetable and flower oils in support of the development of the Registration Review Work Plan.

## RECOMMENDATIONS AND CONCLUSIONS

### Executive Summary

Based on the available data and information, the Agency does not foresee the need for new data or for a new human health risk assessment for these active ingredients. Hazard and exposure information as well as Agency risk assessments on vegetable and flower oils were evaluated against current safety standards established by the Agency's scientific policies and regulations and it was determined that there is no need to conduct an additional human health risk assessment. Flower and vegetable oils are naturally-occurring substances, have non-toxic modes of action (they are primarily repellents) and there is a significant history of exposure to humans and the environment. According to the Incident Data System, there have been no reports of incidents from use of products containing flower and vegetable oils as an active ingredient. There is reasonable certainty that no harm will result to the general population from exposure to flower and vegetable oils in the products containing these active ingredients when they are used according to label instructions.

### **I. Background**

There are seventeen active ingredients classified under flower and vegetable oils. They are the following: Oil of mustard, Canola oil, Oil of citronella, Indole, Soybean oil, Castor oil, Lavandin oil, Oil of lemongrass, Oil of eucalyptus, Oil of orange, Jojoba oil, Eugenol, Balsam Fir Oil, Bergamot oil, 3-Buten-2-one, 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, (E)-, Geraniol, and Oil of thyme.

Twelve of the seventeen active ingredients are currently listed on the 25b list. Seven of the thirteen actives currently have no federally-registered products, and thus will not be included in this toxicity evaluation. The remaining five 25b active ingredients do have federally-registered products, and include the following: Oil of citronella, Soybean oil, Castor Oil, Eugenol, and Geraniol.

Some of the uses for products containing vegetable and flower oils as active ingredients include controlling insects and fungi from fruits, vegetables, nuts, berries, grains, flowers, trees, shrubbery, and cotton; controlling whitefly and powdery mildew; controlling fleas; insect traps; mole repellents; moth repellents; aroma pouches repelling pets from shrubbery; mating disruptants; and sunscreens.

Currently, there are fifty-two end-use products that are registered with BPPD containing these biochemicals. Forty of the products are for residential use, six for agricultural use, and six for both residential and agricultural use. Twenty of the fifty-two products contain only one of these flower and vegetable oils as their active ingredient. The remaining thirty-two products contain additional active ingredients, including pyrethrins, capsaicin, and other flower and vegetable oils.

## II. Tolerances

**§ 180.1127 Biochemical pesticide plant floral volatile attractant compounds: cinnamaldehyde, cinnamyl alcohol, 4-methoxy cinnamaldehyde, 3-phenyl propanol, 4-methoxy phenethyl alcohol, indole, and 1,2,4-trimethoxybenzene; exemptions from the requirement of a tolerance.**

Residues of the biochemical pesticide plant floral volatile attractant compounds: cinnamaldehyde, cinnamyl alcohol, 4-methoxy cinnamaldehyde, 3-phenyl propanol, 4-methoxy phenethyl alcohol, indole, and 1,2,4-trimethoxybenzene are exempt from the requirement of a tolerance in or on the following raw agricultural commodities: the following field crops—alfalfa, clover, cotton, dandelion, peanuts (including hay), rice, sorghum (milo), soybeans, sunflower, sweet potatoes, and wheat; the following vegetable crops—asparagus, beans (including forage hay), beets, carrots, celery, cole crops (cabbage, broccoli, brussels sprouts, cauliflower), collards (kale, mustard greens, turnip greens, kohlrabi), corn, fresh (field, sweet, pop, seed), corn fodder and forage, chinese cabbage, cowpeas, cucurbitis (cucumbers, squash, pumpkin), egg plant, endive (escarole), horseradish (radish, rutabagas, turnip roots), leafy greens (spinach, swiss chard), lettuce (head leaf), okra, parsley, parsnip, peas, peas with pods, peppers, potatoes, sugar beets, tomatoes; the following tree fruit, berry and nut crops—almonds, apples, apricots, berries (blackberry, boysenberry, dewberry, loganberry, raspberry), blueberry, cherry, citrus (grapefruit, kumquat, lemon, lime, orange, tangelo, and tangerine) cranberry, grapes, melons, (watermelon, honeydew, crenshaw, cantaloupe, casaba, persian), nectarines, pears, pecans, peaches, and strawberry as dispersed from the end-use product Corn Rootworm Bait<sup>®</sup>, a pesticidal bait, in accordance with the prescribed conditions in paragraph (a) of this section.

(a) Cumulative yearly application cannot exceed 20 grams of each floral attractant/acre/application.

(b) [Reserved]

[59 FR 15857, Apr. 5, 1994]

**§ 180.1160 Jojoba oil; exemption from the requirement of a tolerance.**

The insecticide and spray tank adjuvant jojoba oil is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied at the rate of 1.0% or less of the final spray in accordance with good agricultural practices, provided the jojoba oil does not contain simmondsin, simmondsin-2-ferulate, and related conjugated organonitriles including demethyl simmondsin and didemethylsimmondsin.

[61 FR 2121, Jan. 25, 1996]



**§ 180.1167 Allyl isothiocyanate as a component of food grade oil of mustard; exemption from the requirement of a tolerance.**

The insecticide and repellent Allyl isothiocyanate is exempt from the requirement of a tolerance for residues when used as a component of food grade oil of mustard, in or on all raw agricultural commodities, when applied according to approved labeling.

[61 FR 24894, May 17, 1996]

**§ 180.1241 Eucalyptus oil; exemption from the requirement of a tolerance.**

Time-limited exemptions from the requirement of a tolerance are established for residues of eucalyptus oil on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of eucalyptus oil will expire and are revoked on June 30, 2007.

[70 FR 37696, June 30, 2005]

**§ 180.1251 Geraniol; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide geraniol in or on all food commodities.

[69 FR 23151, Apr. 28, 2004]

**§ 180.1271 Eucalyptus oil; exemption from the requirement of a tolerance.**

An exemption from the requirement of tolerance is established for residues of eucalyptus oil in or on honey, honeycomb, and honeycomb with honey when used at 2g or less eucalyptus oil per hive, where the eucalyptus oil contains 80% or more eucalyptol.

[71 FR 53979, Sept. 13, 2006]

### **III. Incidents**

Seven of the active ingredients discussed in this registration review had reported incidents (Oil of Mustard, Canola Oil, Oil of Citronella, Eugenol, Geraniol, Lavandin Oil, and Oil of Eucalyptus). The incidents reported for four out of seven of these ingredients (Oil of Mustard, Canola Oil, Eugenol, and Geraniol) contained additional active ingredients to increase overall toxicity of the product, including capsaicin, pyrethrins, 2-phenylethyl propionate, and (r,z)-5-(1-decynyl)dihydro-2(3H)-furanone. Detailed reports for each incident have been extracted and the Agency is currently performing a thorough review of each incident. The Agency intends to look for trends that may indicate any threat to human health. Early indications show that most incidents indicate external factors that likely contributed to the adverse effects noted. In addition, several incidents point to product misuse and symptoms attributable to the other active ingredient(s) in the product. Overall, the incident reports do not indicate any specifically related vegetable and flower oil-related causes. The Agency does not expect any risk associated with these active ingredients because they are either commonly found in foods, are considered GRAS

(Generally Recognized as Safe) by the FDA, or are exempted 25(b) minimum risk pesticides. If the Agency believes there may be risk related to any of the vegetable and flower oils, it will be addressed in the Final Work Plan.

#### **IV. Toxicity Profile**

Although data on the technical grade of the active ingredient (TGAI) are required under 40 CFR 158.2050, because the eight active ingredients that are considered minimum risk pesticides (Castor oil, Lemongrass oil, Citronella oil, Eugenol, Geraniol, Soybean oil, and Thyme oil) and have a significant history of exposure to humans, toxicology data on them historically have been waived. Based on the available information on these biochemicals and their current uses as pesticides, the Agency will continue to waive generic toxicology data requirements for the TGAI. However, toxicology data requirements must be fulfilled for manufacturing products (MPs) end-use products (EPs) containing these active ingredients. Toxicology data and or rationale to fulfill or waive these requirements are available on the currently registered EPs; all of which indicate that these products are of low toxicity.

Vegetable and flower oils are composed of a group of compounds that are natural components of plants. It has been determined that due to the nature of these compounds, it is unlikely that products containing vegetable and flower oils will have adverse effects on human health. All toxicology data requirements have been satisfied and it is unlikely that any additional data will be required. Toxicology data and or rationale to fulfill or waive these requirements are available on the currently registered EPs; all of which indicate that these products are of low toxicity.

Please see the tables below for detailed information regarding the toxicity data requirements.

Available toxicity data as required by 40 CFR 158.2050 regarding Flower and Vegetable Oils are summarized below in Tables 1-7.

Table 1. Vegetable and Flower Oils: Acute Oral Toxicity/OPPTS 870.1100

<u>Active Ingredient</u>	<u>LD<sub>50</sub></u>	<u>Toxicity Category</u>	<u>MRID</u>
<i>Oil of mustard</i>	Lab ALD, 2.85 gm/kg	III	32766
<i>Oil of mustard</i>	> 5,000 mg/kg	IV	41044002
<i>Oil of mustard</i>	> 5,000 mg/kg	IV	41044102
<i>Oil of mustard</i>	> 5,000 mg/kg	IV	41044202
Canola Oil	> 2,000 mg/kg*	III*	44076904
Canola Oil	> 5,000 mg/kg	IV	45737201
Canola Oil	> 5,000 mg/kg	IV	45860601
Canola Oil	> 5,000 mg/kg	IV	47868206
Canola Oil	> 5,000 mg/kg	IV	47868213
<i>Oil of citronella</i>	> 2,500 mg/kg	III	64473
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	96570
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	123620
<i>Oil of citronella</i>	> 5,050 mg/kg	IV	41747402
<i>Oil of citronella</i>	5,000 mg/kg	III	42151304
<i>Oil of citronella</i>	4,800 mg/kg	III	42821504
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	42921307
<i>Oil of citronella</i>	4,380 mg/kg	III	43179401
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	44221202
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	44426402
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	46684705
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	47029305
Indole	1,000 mg/kg	III	47396921
Indole	> 5,000 mg/kg	IV	47406001
<i>Oil of eucalyptus</i>	> 5,000 mg/kg	IV	41581801
<i>Oil of eucalyptus</i>	> 5,000 mg/kg	IV	41939701
<i>Oil of eucalyptus</i>	> 5,000 mg/kg	IV	45687501
Jojoba Oil	>5050 mg/kg	IV	43302503
<i>Eugenol</i>	1,930 mg/kg	III	58667
<i>Eugenol</i>	1,600 mg/kg	III	42347103
3-Buten-2-one, 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, (E)-	4590 mg/kg	III	46221503
<i>Lavandin Oil</i>	> 5,000 mg/kg	IV	From science review R134742
Balsam Fir Oil	> 5,000 mg/kg	IV	46784402

\* 2,000 mg/kg was the highest dose tested in the study



Table 2. Vegetable and Flower Oils: Acute Dermal Toxicity/OPPTS 870.1200

<u>Active Ingredient</u>	<u>LD<sub>50</sub></u>	<u>Toxicity Category</u>	<u>MRID</u>
<i>Oil of mustard</i>	> 2,000 mg/kg*	III*	41044001
<i>Oil of mustard</i>	> 2,000 mg/kg*	III*	41044101
<i>Oil of mustard</i>	> 2,000 mg/kg*	III*	41044201
Canola Oil	> 2,000 mg/kg*	III*	44076905
Canola Oil	> 5,000 mg/kg	IV	45737202
Canola Oil	> 5,000 mg/kg	IV	45860602
Canola Oil	> 5,000 mg/kg	IV	47868207
<i>Oil of citronella</i>	> 2,000 mg/kg*	III*	130230
<i>Oil of citronella</i>	> 2,000 mg/kg*	III*	131243
<i>Oil of citronella</i>	> 2,000 mg/kg*	III*	42151305
<i>Oil of citronella</i>	> 2,000 mg/kg*	III*	43167101
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	44414801
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	46684706
<i>Oil of citronella</i>	> 5,000 mg/kg	IV	47029306
Indole	790 mg/kg	II—no study done, based on supplier's MSDS	47396921
<i>Lavandin Oil</i>	> 5,000 mg/kg	IV	44309901
Oil of eucalyptus	> 2,000 mg/kg*	III*	131243
Oil of eucalyptus	> 2,000 mg/kg*	III*	41581805
Oil of eucalyptus	> 2,000 mg/kg*	III*	41581809
Oil of eucalyptus	> 2,000 mg/kg*	III*	41939704
Oil of eucalyptus	> 2,000 mg/kg*	III*	41939707
Oil of eucalyptus	5,000 mg/kg	III-	45540102
<i>Jojoba Oil</i>	> 2,020 mg/kg*	III	43302504
Eugenol	1000 mg/kg	II—guideline study	42347104
<i>3-Buten-2-one, 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, (E)-</i>	2270 mg/kg	III	46221503
Lavandin Oil	> 5,000 mg/kg	IV	From science review R134742
Balsam Fir Oil	> 5,000 mg/kg	IV	46784403

\* 2,000 mg/kg was the highest dose tested in the study

Table 3. Vegetable and Flower Oils: Acute Inhalation Toxicity/OPPTS 870.1300

<u>Active Ingredient</u>	<u>LC<sub>50</sub></u>	<u>Toxicity Category</u>	<u>MRID</u>
<i>Oil of mustard</i>	> 4.21 mg/L	IV	41044001
<i>Oil of mustard</i>	> 4.21 mg/L	IV	41044201
Canola Oil	> 2.36 mg/L	IV	44157701
<i>Oil of citronella</i>	> 5.68 mg/L	IV	41747404
<i>Oil of citronella</i>	> 5.45 mg/L	IV	42151306
<i>Oil of citronella</i>	> 5.04 mg/L	IV	42921304
<i>Oil of citronella</i>	> 3.01 mg/L	IV	43167102
<i>Oil of citronella</i>	> 2.2 mg/L	IV	44426403
<i>Oil of citronella</i>	> 2.06 mg/L	IV	47029307
Lavandin Oil	> 1.1 mg/L	III	44309902
<i>Eugenol</i>	> 0.77 mg/L	III	41614411
Balsam Fir Oil	> 2.07 mg/L	IV	46784404



Table 4. Vegetable and Flower Oils: Acute Eye Irritation/OPPTS 870.2400

<u>Active Ingredient</u>	<u>Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
<i>Oil of mustard</i>	<i>Positive chemosis in 6/6 rabbits 1 hr after dosing; Conjunctival erythema in 3/6 rabbits after 24 hrs and 2/6 positive chemosis; all irritation cleared by Day 4</i>	<i>III</i>	<i>44052501</i>
<i>Oil of mustard</i>	<i>Moderate conjunctival erythema (6/6 rabbits)</i>	<i>III</i>	<i>41044002</i>
<i>Oil of mustard</i>	<i>Moderate conjunctival erythema (6/6)</i>	<i>III</i>	<i>41044102</i>
<i>Oil of mustard</i>	<i>Moderate conjunctival erythema (6/6)</i>	<i>III</i>	<i>41044202</i>
Canola Oil	Slight irritation (3/3 r)	IV	44076906
Canola Oil	Slight irritation (3/3)	IV	47868209
<i>Oil of citronella</i>	<i>Hyperemia and chemosis (4/6)</i>	<i>III</i>	<i>130230</i>
<i>Oil of citronella</i>	<i>Slight conjunctival erythema (6/9)</i>	<i>III</i>	<i>131244</i>
<i>Oil of citronella</i>	<i>Moderate conjunctival erythema</i>	<i>III</i>	<i>41747405</i>
<i>Oil of citronella</i>	<i>Slight irritation</i>	<i>IV</i>	<i>42151307</i>
<i>Oil of citronella</i>	<i>Slight irritation</i>	<i>IV</i>	<i>42821504</i>
<i>Oil of citronella</i>	<i>Moderate conjunctival erythema</i>	<i>III</i>	<i>42921306</i>
<i>Oil of citronella</i>	<i>Moderate conjunctival erythema</i>	<i>III</i>	<i>43167103</i>
<i>Oil of citronella</i>	<i>Slight irritation</i>	<i>IV</i>	<i>42890103</i>
<i>Oil of citronella</i>	<i>Slight irritation (3/3)</i>	<i>III</i>	<i>44133101</i>
<i>Oil of citronella</i>	<i>Slight irritation (6/6)</i>	<i>III</i>	<i>44238502</i>
<i>Oil of citronella</i>	<i>Slight irritation (3/3)</i>	<i>III</i>	<i>44397601</i>
<i>Oil of citronella</i>	<i>Slight irritation (3/3)</i>	<i>III</i>	<i>44414802</i>
<i>Oil of citronella</i>	<i>Slight irritation (6/6)</i>	<i>III</i>	<i>44426405</i>
<i>Oil of citronella</i>	<i>Slight irritation (3/3)</i>	<i>III</i>	<i>46684703</i>
<i>Oil of citronella</i>	<i>Slight irritation (3/3)</i>	<i>III</i>	<i>47029308</i>
Indole	Slight irritation (3/3)	III	151040
Soybean Oil	Slight irritation (3/3)	III	42149501
Soybean Oil	Slight irritation (3/3)	III	94327001
<i>Oil of eucalyptus</i>	<i>Slight irritation (6/9)</i>	<i>III</i>	<i>131244</i>
<i>Oil of eucalyptus</i>	<i>No effects</i>	<i>IV</i>	<i>41581802</i>
<i>Oil of eucalyptus</i>	<i>Slight irritation (3/3)</i>	<i>III</i>	<i>41581806</i>

<i>Oil of eucalyptus</i>	<i>No effects</i>	<i>IV</i>	<i>41581810</i>
<i>Oil of eucalyptus</i>	<i>No effects</i>	<i>IV</i>	<i>41939702</i>
Lavandin Oil	Moderate irritation	III	From science review R134742
<i>Balsam Fir Oil</i>	<i>Mild irritation</i>	<i>IV</i>	<i>46784405</i>
Jojoba Oil	Mild irritation	IV	Internal memo from J. Anderson to D. Barolo (12/15/95)

Table 5. Vegetable and Flower Oils: Acute Dermal Irritation/OPPTS 870.2500

<b><u>Active Ingredient</u></b>	<b><u>Results at 72 hrs</u></b>	<b><u>Toxicity Category</u></b>	<b><u>MRID</u></b>
<i>Oil of mustard</i>	<i>Mild irritation</i>	<i>IV</i>	44052502
<i>Oil of mustard</i>	<i>No effects</i>	<i>IV</i>	41044102
<i>Oil of mustard</i>	<i>No effects</i>	<i>IV</i>	41044002
<i>Oil of mustard</i>	<i>No effects</i>	<i>IV</i>	41044202
Canola Oil	Moderately irritating	III	44076907
Canola Oil	Slight irritation at 24 hrs	IV	46147704
Canola Oil	Very slight irritation at 72 hrs	IV	47868210
<i>Oil of citronella</i>	<i>No effects</i>	<i>IV</i>	131243
<i>Oil of citronella</i>	Very slight irritation at 72 hrs	IV	41747406
<i>Oil of citronella</i>	Very slight irritation at 72 hrs	IV	42151308
<i>Oil of citronella</i>	<i>No effects</i>	<i>IV</i>	42821504
<i>Oil of citronella</i>	<i>Moderately irritating</i>	<i>III</i>	42921309
<i>Oil of citronella</i>	<i>No effects</i>	<i>IV</i>	43167104
<i>Oil of citronella</i>	<i>No effects</i>	<i>IV</i>	42890103
<i>Oil of citronella</i>	<i>Slight irritation at 24 hrs</i>	<i>IV</i>	44238503
<i>Oil of citronella</i>	<i>Very slight irritation at 24 hrs</i>	<i>IV</i>	44397602
<i>Oil of citronella</i>	<i>Moderate irritation at 72 hrs</i>	<i>III</i>	47029309
<i>Oil of citronella</i>	<i>No effects</i>	<i>IV</i>	47893202
Indole	Very slight irritation at 72 hrs	IV	151039
<i>Oil of eucalyptus</i>	<i>Slight irritation at 72 hrs</i>	<i>IV</i>	131243
<i>Oil of eucalyptus</i>	<i>No effects</i>	<i>IV</i>	41581803
<i>Oil of eucalyptus</i>	<i>No effects</i>	<i>IV</i>	41939703
<i>Oil of eucalyptus</i>	<i>No effects</i>	<i>IV</i>	47624105
Jojoba Oil	<i>No effects</i>	<i>IV</i>	43302506
Eugenol	Severe irritation at 72 hrs	II	42347105
3-Buten-2-one, 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-, (E)-	Moderate irritation at 72 hrs	III	46221503
Lavandin Oil	Slight irritation at 72 hrs	IV	From science review R134742
Balsam Fir Oil	Severe irritation at 72 hr	II	46784406



Table 6. Vegetable and Flower Oils: Skin Sensitization/OPPTS 870.2600

<u>Active Ingredient</u>	<u>Results</u>	<u>MRID</u>
<i>Oil of mustard</i>	<i>Weak sensitizing agent</i>	41532902
<i>Oil of mustard</i>	<i>Not a sensitizing agent</i>	41080101
Canola Oil	Not a sensitizing agent	47868211
Canola Oil	May cause sensitization	47868212
<i>Oil of citronella</i>	<i>Sensitizing agent</i>	41747407
<i>Oil of citronella</i>	<i>Not a sensitizing agent</i>	42151309
<i>Oil of citronella</i>	<i>Not a sensitizing agent</i>	42921308
<i>Oil of citronella</i>	<i>Not a sensitizing agent</i>	43167105
<i>Oil of citronella</i>	<i>Weak sensitizing agent</i>	44397603
<i>Oil of citronella</i>	<i>Not a sensitizing agent</i>	44414803
<i>Oil of citronella</i>	<i>Sensitizing agent</i>	46684707
<i>Oil of citronella</i>	<i>Sensitizing agent</i>	47029310
<i>Oil of citronella</i>	<i>Not a sensitizing agent</i>	47893202
Oil of eucalyptus	<i>Non/weak sensitizing agent</i>	41581807
Oil of eucalyptus	<i>Moderate Sensitizing agent</i>	41581811
Oil of eucalyptus	<i>Weak sensitizing agent</i>	41939705
Oil of eucalyptus	<i>Moderate Sensitizing agent</i>	41939708
<i>Eugenol</i>	<i>Not a sensitizing agent</i>	124457
Lavandin Oil	Not a sensitizing agent	From science review R134742
<i>Balsam Fir Oil</i>	<i>Sensitizing Agent</i>	46784407
Jojoba Oil	Not a sensitizing agent	"Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax"*

\*CTFA, 1988 as reported in Diener, Robert M., ed., 1992. "Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax. Nineteenth Report of the Cosmetic Ingredient Review Expert Panel." J. American College of Toxicology, Vol. 11(1): 57-82.

Table 7. Vegetable and Flower Oils: 90-Day Oral Toxicity/OPPTS 870.3100

<u>Active Ingredient</u>	<u>LD<sub>50</sub></u>	<u>Toxicity Category</u>	<u>MRID</u>
<i>Oil of mustard</i>	> 25 mg/kg (5 times a week for 13 weeks)	No effects observed	46252501

Table 8. Vegetable and Flower Oils: Prenatal Development Toxicity Study/ OPPTS 870.3700

<u>Active Ingredient</u>	<u>Results</u>	<u>MRID</u>
Oil of mustard	No anomalies when given 60 mg/kg; no increase in fetal deaths	46252501
Oil of mustard	No effect at 6 mg/kg; at 28 mg/kg, increased fetal deaths and resorptions	47049303

Table 9. Vegetable and Flower Oils: Chronic Toxicity/OPPTS 870.4100

<u>Active Ingredient</u>	<u>Results</u>	<u>MRID</u>
Oil of mustard	2-yr carcinogenesis bioassay 12 or 25 mg/kg 5 times per week to 50 rats and 50 mice of each sex; carcinogenic for male rats	46252501

Table 10. Vegetable and Flower Oils: Bacterial Reverse Mutation Test/OPPTS 870.5100

<u>Active Ingredient</u>	<u>Results</u>	<u>MRID</u>
Eugenol	negative	41614416
Eugenol	negative	41614417
Eugenol	negative	41614418
Eugenol	negative	41614419
Eugenol	negative	41614421

Available acute toxicity data on the EP's indicates that most fifty-two products fall into Toxicity Category III or IV for all routes of exposure.

Data gaps currently exist for the following active ingredients:

<u>Active Ingredient</u>	<u>Toxicity Data Requirements</u>
Indole	Acute Inhalation Toxicity; Skin Sensitization
Jojoba Oil	Acute Inhalation Toxicity

All toxicology data for indole were waived based on the fact that this ingredient is naturally occurring, has a non-toxic mode of action, will not accumulate in the environment, and due to the nature of the product (trap), there is no anticipated exposure. In addition, based on exposure and toxicity information, no adverse human health effects are expected when jojoba oil is used as a

pesticide.

It is anticipated that these data gaps will be addressed by researching the publicly-available scientific literature. Based on vegetable and flower oils' physical and chemical properties, they are considered to be non-persistent in the environment. They degrade rapidly in the environment and therefore, human exposure to pesticidal residues is expected to be minimal.

Based on the information presented above, the Agency does not foresee the need for new data or for a new human health risk assessment. There is reasonable certainty that no harm will result to the general population from exposure to vegetable and flower oils in the products containing these active ingredients when they are used according to label instructions.

## **V. References**

U.S. EPA RED Fact Sheet for Flower and Vegetable Oils. Issued December, 1993.

U.S. EPA RED-Flower and Vegetable Oils. Issued December, 1993.

cc: *S. Shaukat, M. Adams*, BPPD Science Review File  
*S. Shaukat*, FT, PY-S: 2/19/10